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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,054	08/30/2001	Seiichi Araki	109536-161	8743

23483 7590 12/26/2006

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	12/26/2006	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 12/26/2006.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/943,054	ARAKI ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 55-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 55-57* is/are rejected.

7)☒ Claim(s) 7 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/420,632.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 9/8/2006, have been fully considered but are deemed moot in light of the cancellation of claims 10-54. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is James D. Anderson, Ph.D. Contact information is provided at the end of this Office Action.

Status of the Claims

Claims 1-9 and 55-57 are currently pending and are the subject of this Office Action.

Maintenance Fees

Examiner notes that the 7.5-year maintenance fees for U.S. Patent No. 5,945,420, issued August 31, 1999, of which the instant application is a reissue, are due in February 2007.

Defective Oath

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following: the subject matter of newly added claims 55-57,

drawn to a method of treating infections caused by *Escherichia coli*, was not identified as an error in the originally filed oath/declaration. A supplemental oath/declaration is required.

Application Objections

This application is objected to under 37 CFR § 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172*(a). The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR § 3.73(b).

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

The person who signed the submission establishing ownership interest has failed to state his/her capacity to sign for the corporation or other business entity, and he/she has not been established as being authorized to act on behalf of the assignee, *e.g.* the Title of the person signing was left blank. See MPEP § 324.

Similarly, the Consent of Assignee, filed 4/15/2002 is objected to because the title of the person signing on behalf of the assignee was left blank.

Claim Objections

Claim 7 is objected to because of the following informalities: the words "chondroitinn" and "faty" are misspelled in line 4 and the word "polyvinlyl" is misspelled in line 5. The correct

spellings are ---chondroitin---, ---fatty---, and ---polyvinyl---, respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 55-57 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for increasing the immune response of animals inoculated with *Escherichia coli (E. coli)*, does not reasonably provide enablement for "protecting against" infections generally or specifically treating *E. coli* infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

The instant claims are drawn to a method for "protection against infection" (claims 1-8) and treating infections caused by *E. coli* (claims 9 and 55-57) by administering a composition comprising riboflavin and/or a riboflavin derivative. Dependent claims recite further additives (*e.g.* antibiotics and water-soluble polymers). For the instant rejection, the limitation "protection from infection" is interpreted to mean that administration of the claimed compounds, prior to an infection, prevents a patient from *developing* an infection. This interpretation is supported by the examples in the Specification wherein riboflavin is injected prior to inoculation with *E. coli* (columns 5 to 8) and survival rate monitored. As such, instant claims 1-8, in their broadest

reasonable interpretation, are drawn to methods of preventing any and all infections. Said infections would include viral infections (*e.g.* AIDS, the common cold, chicken pox, hepatitis, etc.), bacterial infections (*e.g.* anthrax, bacterial meningitis, cholera, syphilis, etc.), parasitic infections (*e.g.* malaria, trichinosis, pinworm infection, etc.), fungal infections (*e.g.* aspergillosis) and prion infections (*e.g.* transmissible spongiform encephalopathy). It is noted that applicants have placed no limitations on the types of infections to be treated, either in the specification or the claims. Clearly, applicants are not enabled for the prevention, or even the treatment, of the common cold by administering riboflavin (*i.e.* Vitamin B_2). It is also noted that there is currently no prevention of (*i.e.* protection against), for example, the common cold and AIDS in the prior art.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) The breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to the protection against infection or treatment of *E. coli* infections by administering riboflavin or a derivative of riboflavin. The relative skill of those in the art is

high, generally that of an M.D. or Ph.D. That factor is outweighed, however, by the unpredictable nature of the art. For example, there is no known preventative agent for AIDS or the common cold. The art of *treating* infections, particularly in humans, is generally unpredictable due to the broad nature of the causes of infection. This is especially true with respect to a single agent being able to treat (let alone prevent) all types of infection, regardless of cause (*e.g.* viral, bacterial, parasitic, fungal, etc.) or etiology. It is well known in the art that infections of different origins (*i.e.* viral, parasitic, bacterial, fungal, etc.) have different etiologies and treatment regimens. For example, the skilled artisan would not use an antibiotic to treat a viral infection because it is well known in the art that antibiotics have minimal effect in treating viral infections.

2. The breadth of the claims

The claims are extremely broad, being drawn to the protection against any and all infections by administering riboflavin (*i.e.* Vitamin B_2) and treating *E. coli* infections.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimens (*e.g.* dosages, timing, administration routes, etc.) necessary to treat, let alone "protect against" (*i.e.* prevent), all infections, and particularly in humans. The working examples are limited to the effects of riboflavin on the survival rate of mice inoculated with a single type of bacteria, *E. coli*. Thus, the applicant at best only demonstrated that riboflavin

administered prior to an *E. coli* infection might boost the immune response of said animal. There is no indication that the mice inoculated with *E. coli* were prevented from becoming infected (*i.e.* prevention of infection) or that they were treated (i.e. *E. Coli* eradicated or rendered impotent), only that the mice survived longer than untreated mice.[2] No reasonably specific guidance is provided concerning useful therapeutic protocols for any other infections (*e.g.* viral infections, parasitic infections, fungal infections, or any other type of bacterial infection).

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that riboflavin could be predictably used as a treatment or prevention for all infections as inferred in the claims and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 1, 3-9 and 55-57 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the

[2] Examiner notes that a treatment of an infection would naturally result in the eradication of or rendering impotent the cause of the infection, whether it is a parasite, bacteria, virus, or fungus.

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The instant claims recite "riboflavin derivative", "antibiotic" and "water-soluble polymer". There is insufficient written description for these agents.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes two species of the instantly claimed "riboflavin derivative" at column 3, lines 48-49 (*e.g.* flavin mononucleotide and flavin adenine dinucleotide), it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by "riboflavin derivative". Further, there is no guidance or direction for methods of identifying, synthesizing, isolating or purifying riboflavin derivatives, other than the two specifically named in the disclosure. As such, the disclosure lacks adequate written description for the limitation "riboflavin derivative".

Similarly, while the specification describes three examples of "antibiotics" that may be used in the invention at column 4, lines 4-8 (*e.g.* amoxicillin, tetracycline and oxycycline hydrochloride), it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by "antibiotic". Further, there is no guidance or direction for methods

of identifying, synthesizing, isolating or purifying antibiotics, other than the three specifically named in the disclosure. As such, the disclosure lacks adequate written description for the limitation "antibiotic".

Finally, while the specification describes several species of "water-soluble polymers" that may be used in the invention at column 4, lines 29-36 (*e.g.* polyvinyl pyrrolidone, methyl cellulose, hydroxypropyl cellulose, etc.), it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by "water-soluble polymer". Further, there is no guidance or direction for methods of identifying, synthesizing, isolating or purifying water-soluble polymers, other than polymers specifically named in the disclosure. As such, the disclosure lacks adequate written description for the limitation "water-soluble polymers".

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, the claims recite the limitation "protection against infection". Although examiner has interpreted this limitation to mean "prevention" of infection, the metes and bounds of this claim limitation are still unclear. For example, is it applicants' intent that "protection against infection" means treating (*i.e.* eradicating or rendering impotent) the infection? The specification does not aid in interpreting this claim limitation.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wertman and Sypherd (J. Immunol., 1960, vol. 85, pages 511-515).

The instant claim is drawn to "protection against infection" comprising administering riboflavin. Dependent claims 4 and 5 recite specific doses and administration routes, respectively.

Wertman and Sypherd evaluated the effects of riboflavin deficiency on rat susceptibility to infection with *Diplococcus pneumoniae* (Table III). *Ad libitum* rats were fed a basal diet *ad libitum* with a vitamin supplement containing 60 μg riboflavin (page 512). Rats initially weighed 34-35 g (Table I). Thus, the dose of riboflavin administered falls in the instantly claimed range (*i.e.* 1.7 mg/kg). Inanition control rats received only enough basal diet to maintain their weights equal to those of the riboflavin deficient animals (*id.*). Deficient animals received the basal diet ad libitum without a vitamin supplement (*id.*). At the end of 7 weeks, rats were challenged with virulent *D. pneumonie* (page 513). 83.3% of riboflavin deficient rats died compared to only 33.3% inanition rats and 0.0% *ad libitum* control rats (Table III). Riboflavin deficient rats fed 60 mg of riboflavin daily for 1 week following the 7-week riboflavin deficient diet and subsequently challenged with *D. pneumonie* only showed 9.1% fatality. Clearly, riboflavin "protected against infection" in the riboflavin treated rats. With respect to instant claim 2, which recites administration of the coenzyme flavin mononucleotide or flavin dinucleotide, the reference inherently teaches this limitation because administration of riboflavin

will naturally result in the production of these two coenzymes, as riboflavin is enzymatically converted to flavin mononucleotide, which then forms flavin dinucleotide.

The reference thus teaches that administration of riboflavin, in the doses and administration routes instantly claimed, protects rats from dying from an infection of *D. pneumonie.*

Claims 1, 2 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ajayi *et al.* (Eur. J. Haematol., 1990, vol. 44, pages 209-212).

Claim 1 is drawn to "protection against infection" comprising administering riboflavin.

Ajayi *et al.* administered riboflavin (5 mg) as a dietary supplement to 27 young Nigerian adults. Vitamin supplementation produced a significant hematological response, including increased hemoglobin concentration, hemocrit level and erythrocyte count (Abstract). The authors conclude that, even in malarial infection, hemoglobin concentration, hemocrit level and erythrocyte count were maintained if high vitamin (*i.e.* riboflavin) status was established throughout supplementation. Erythropoiesis is reported to be impaired in infection, and malaria parasitaemia alters hematological status (page 211). In the present study, successful control of malaria was not achieved with pyrimethamine, but high riboflavin status helped to maintain hemoglobin concentration and red blood cell count during malarial infection (*id.*). With respect to instant claim 2, which recites administration of the coenzyme flavin mononucleotide or flavin dinucleotide, the reference inherently teaches this limitation because administration of riboflavin will naturally result in the production of these two coenzymes, as riboflavin is enzymatically converted to flavin mononucleotide, which then forms flavin dinucleotide.

Thus, the reference teaches administration of riboflavin to patients with a malarial infection leads to a significant hematological response. The instantly claimed "protection against infection" would inherently result from the method steps of the reference.

Claims 1, 2, 3 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tsyganenko (Vopr. Med. Khim., 1971, vol. 17, pages 364-369).[3]

Claim 1 is drawn to "protection against infection" comprising administering riboflavin or a combination of riboflavin and an antibiotic.

Tsyganenko teach that *Staphylococcal* necrotic infections decrease the activity of mitochondrial monoamine oxidase (MAO) (Abstract). Infected animals treated with the antibiotic, tetracycline, exhibited further inhibition of staphylotoxin-repressed MAO activity (*id.*). Treatment of animals with tetracycline in combination with vitamins B_2 and B_{12} ensured a restoration of MAO activity, repressed by antibiotics, to the level of non-treated animals (*id.*). The best stimulatory activity was observed with the combination of penicillin and vitamin B_2. In this case, MAO activity was higher in rabbits receiving antibiotics only and was restored to the level of enzyme activity in intact animals (*id.*). With respect to instant claim 2, which recites administration of the coenzyme flavin mononucleotide or flavin dinucleotide, the reference inherently teaches this limitation because administration of riboflavin will naturally result in the production of these two coenzymes, as riboflavin is enzymatically converted to flavin mononucleotide, which then forms flavin dinucleotide.

[3] The cited article is in Russian. The Abstract of said article is attached and used as prior art in the present rejection.

Thus, the reference teaches administration of riboflavin in combination with an antibiotic to animals with an infection (*Staphyloccal* necrotic infection). The instantly claimed "protection against infection" would inherently result from the method steps of the reference.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zoltowska *et al.* (Wiad Parazytol., 1991, vol. 37, pages 247-253).[4]

Claim 1 is drawn to "protection against infection" comprising administering riboflavin.

Zoltowska *et al.* administered vitamin B_2 (1 mg) to guinea pigs and on the 9th day, post vitamin administration, the guinea pigs were infected with 5000 invasive eggs of *Ascaris suum* (Abstract).[5] The invasion lasted 6 days and was monitored by lung and kidney weight as well as the number of larvae in the lungs (*id.*). With respect to instant claim 2, which recites administration of the coenzyme flavin mononucleotide or flavin dinucleotide, the reference inherently teaches this limitation because administration of riboflavin will naturally result in the production of these two coenzymes, as riboflavin is enzymatically converted to flavin mononucleotide, which then forms flavin dinucleotide.

Thus, the reference teaches administration of riboflavin to animals prior to infection with *Ascaris suum*. The instantly claimed "protection against infection" would inherently result from the method steps of the reference. This is because the reference teaches administration of riboflavin prior to an infection.

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[4] The cited article is in Polish. The Abstract of said article is attached and used as prior art in the present rejection.
[5] *Ascaris suum* is a large roundworm parasite found in pigs.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Folkers *et al.* (Proc. Natl. Acad. Sci. USA, 1984, vol. 81, pages 7076-7078).

Claim 1 is drawn to "protection against infection" comprising administering riboflavin.

Folkers *et al.* orally administered 50 mg/day riboflavin to patients with carpal tunnel syndrome. With respect to instant claim 2, which recites administration of the coenzyme flavin mononucleotide or flavin dinucleotide, the reference inherently teaches this limitation because administration of riboflavin will naturally result in the production of these two coenzymes, as riboflavin is enzymatically converted to flavin mononucleotide, which then forms flavin dinucleotide.

Thus, the reference teaches administration of riboflavin to those who had no prior infection. The instantly claimed "protection against infection" would inherently result from the method steps of the reference. This is because the reference teaches administration of riboflavin prior to an infection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/472,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 encompasses the subject matter claimed in the conflicting application when a "riboflavin derivative" is administered. The method described in claim 14 of the '621 application is drawn to a method of infection protection which comprises administering reduced riboflavin to a subject. The reduced riboflavin recited in claim 14 of the '621 is a "riboflavin derivative" as recited in instant claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Phyllis Spivack

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

December 13, 2006